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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,865	10/09/2003	Ragina Naidu	740082.405	7897

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EXAMINER

BERCH, MARK L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/683,865

Applicant(s)

NAIDU, RAGINA

Examiner

Mark L. Berch

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-126 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 43, drawn to cyclization of imines, classified in class 540, subclass 354,360.
- II. Claims 5-6, 44-46, drawn to 3-monosubstituted azetidinones, classified in class 540, subclass 200, 354, 360, 357.
- III. Claims 7-13, 29-31, 47, drawn to ring-opening, classified in class 562, subclass 443, 444, 556, 567 and others.
- IV. Claims 14-16, 32-33, 35-38, 48-50, drawn to isoserines, classified in class 562; 560 subclass 443, 444, 556, 567; 39.
- V. Claims 17-19, drawn to cyclization of aldehydes, classified in class 540, subclass 360.
- VI. Claims 19-21, drawn to halogenation, classified in class 540, subclass 360.
- VII. Claims 22-23, 26-28, drawn to 3,3-disubstituted azetidinones, classified in class 540, subclass 360.
- VIII. Claims 24-25, drawn to displacement reaction, classified in class 540, subclass 360.
- IX. Claim 34, drawn to desulphurization, classified in class 562, 560, subclass 444, 39.
- X. Claims 39-42, drawn to N-acylation process, classified in class 540, subclass 360.

Art Unit: 1624

- XI. Claims 51-61, drawn to displacement of thioaryl, classified in class 562, 560, subclass 444, 39.
- XII. Claims 62-62 and 86 (part), 87-101, 117-126 (part) Esterification, drawn to esterification, classified in class 549, subclass 214, 510.
- XIII. Claims 66-70, drawn to taxane esters, classified in class 549, subclass 214, 510.
- XIV. Claims 71-73, drawn to hydroxylation, classified in class 549, subclass 214, 510.
- XV. Claims 74-78, drawn to taxotere synthesis, classified in class 549, subclass 214, 510.
- XVI. Claim 79, drawn to copper catalyzed acyloxylation, classified in class 540, subclass 357.
- XVII. Claims 80-85, drawn to coupling process with ring-opening, classified in class 549, subclass 214, 510.
- XVIII. Claims 80-85, and 86 (part), 102-116, 117-126 (part) drawn to coupling process with ring-opening, classified in class 549, subclass 214, 510.

In addition, if applicants elect any of Groups III, IV, IX, XI-XV or XVII, a tentative election of a single species is required.

The inventions are distinct, each from the other because of the following reasons:

The processes are distinct from each other, as each involves very different types of chemical reactions, as well as employing different types of reagents.

The compound groups are distinct as seen by their structural differences. For example, the taxanes have a tetracyclic heterocyclic ring system, the azetidinones have one  $\beta$ -lactam ring, and the isoserines have no heterocyclic rings at all.

Inventions I & V and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case there are obviously two methods, since two are given. In addition, these can be made via a conventional cyclization of the  $\beta$ -amino acid chloride.

Inventions VI and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one can do a conventional cyclization of the  $\beta$ -amino acid chloride with the X substituent already present, or one can do a displacement of the 3,3-dihalo azetidinone.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the isoserines can be made by displacement of a  $\beta$ -halo with the amino reactant.

Inventions XII & XVIII and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(d)). In the instant case there are clearly two methods, since two are given. In addition, the compounds can be made by the acyloxylation of the halo-taxane.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. A separate search in electronic databases would be needed for these diverse groups as well.

A telephone call was made to Karl Hermanns on 9/10/2005 to request an oral election to the above restriction requirement, but did not result in an election being made. A written restriction was requested.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch  
Primary Examiner  
Art Unit 1624

9/16/05